Standard Operating Procedures (SOP)
Commerce Research Ethics Committee (COM REC)

Title	Standard Operating Procedures, Commerce Research Ethics Committee (COM REC)
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Person(s) responsible for drafting, review and revision	COM REC Interim Chair COM REC Servicing Officer, for administrative support
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Approving body	COM REC; and sent to EiRC for noting
Relevant related policies, procedures and guidelines	• Terms of Reference, Commerce Research Ethics Committee (COM REC) • UCT Policy for Responsible Conduct of Research • UCT Research Ethics Code for Research Involving Human Participants • Register of Ethics Approvals for Research Conducted under the Auspices of UCT • Code for UCT Research Ethics Committee Members • Appeal to Ethics in Research Committee: Standard Operating Procedure • Conflict of Interest Policy • Policy and Standard Operating Procedure: Ethics Clearance and Permission to Engage UCT Staff and/or Students or their Data in Research • UCT Policy and Procedures for Breach of Research Ethics Codes and Allegations of Misconduct in Research • EiRC Recommendations: Standard criteria for inclusion in research invitations • UCT Guideline for Risk-Based Ethical Review of Research (Human Participants) • EiRC Guidelines and recommendations for the use of generative artificial intelligence (AI) tools in research • UCT Whistleblowing Policy • UCT Research Data Management Policy • The Commerce Practice Note on secondary data

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Commerce Research Ethics Committee (COM REC) Standard Operating Procedures

1. Purpose and Scope

To ensure the protection of human rights and the well-being of human research participants based on ethical and integrity principles and norms, and compliance with the highest ethical standards in social and scientific research, including matters involving authorship and research misconduct, but excluding research involving animals.[1]

2. Delegated authority of the committee

The Commerce Research Ethics Committee (COM REC) has been established to review and take decisions on ethics applications it receives from University of Cape Town staff and students in the Faculty of Commerce under delegated authority of the Dean of the Faculty of Commerce, and the Commerce Faculty Board.

Furthermore, the Dean and Commerce Faculty Board, recognise the independence of the Commerce REC to make decisions within the scope of its terms of reference, standard operating procedures, institutional policies and international and national laws, with no undue influence or interference placed on the committee. The COM REC Standard Operating Procedures are determined by the Committee, to assist it in ensuring that its processes and procedures are fair and consistent. The Faculty Board will be alerted to substantive modifications and amendments to the COM REC Standard Operating Procedures by means of publication in Dean's Circulars.

The COM REC's Terms of Reference and the Standard Operating Procedures, along with other guidance and practice notes, will be published and kept up to date on the Commerce Faculty's website.

3. Definitions

Confidentiality is defined as "the responsibility to protect information entrusted to researchers for research purposes from unauthorized access, use, disclosure, modification, loss or theft".[2]

A **Conflict of Interest** is defined as "incompatibility of duties, responsibilities or interests (personal or professional) of a person or an institution as regards ethical conduct of research so that one cannot be fulfilled without compromising another" [3]

Health Research contributes to knowledge of biological, clinical, psychological, or social welfare matters including processes; causes and effects of and responses to diseases; effects of environment on

[1] Adapted from the Senate Ethics in Research Committee Terms of Reference (2023, https://uct.ac.za/sites/default/files/content_migration/uct_ac_za/87/files/SENATE_ETHICS_IN_RESEARCH_COMMITTEE_ToR.pdf)

[2] National Health Research Ethics Council (2015, https://www.health.gov.za/wp-content/uploads/2022/05/NHREC-DoH-2015-Ethics-in-Health-Research-Guidelines-1.pdf)

[3] National Health Research Ethics Council (2015, https://www.health.gov.za/wp-content/uploads/2022/05/NHREC-DoH-2015-Ethics-in-Health-Research-Guidelines-1.pdf)

humans; methods to improve health care delivery; new pharmaceuticals, medicines, interventions and devices; new technologies to improve health and health care.[4,5]
For the avoidance of any doubt, the South African National Health Act (61 of 2003) defines health research as including any research which "contributes to knowledge of -

(a) the biological, clinical, psychological or social processes in human beings;
(b) improved methods for the provision of health services;
(c) human pathology;
(d) the causes of disease;
(e) the effects of the environment on the human body;
(f) the development or new application of pharmaceuticals, medicines and
(g) the development of new applications of health technology"

Informed consent is one of the founding principles of research ethics. Its intent is that human participants can enter research freely (voluntarily) with full information about what it means for them to take part, and that they give consent before they enter the research.

Consent should be obtained before the participant enters the research (prospectively), and there must be no undue influence on participants to consent. The minimum requirements for consent to be informed are that the participant understands what the research is and what they are consenting to.

There are two distinct stages to a standard consent process for competent adults:

- Stage 1 (giving information): the person reflects on the information given; they are under no pressure to respond to the researcher immediately.

- Stage 2 (obtaining consent): the researcher reiterates the terms of the research, often as separate bullet points or clauses; the person agrees to each term (giving explicit consent) before agreeing to take part in the project as a whole.[6]

A **Principal investigator** (PI) is defined as the person(s) in charge of a clinical trial or a scientific research project. The PI is primarily responsible for the preparation, conduct, and administration of a research grant, cooperative agreement, or other sponsored project in compliance with applicable laws and regulations and institutional policy governing the conduct of research."[7]

Research includes a range of activities conducted by many different disciplines that may use different methodologies and explanatory frameworks to extend or produce knowledge through disciplined inquiry or systematic investigation.

Research data are the information needed 'to support or validate a research project's observations, findings or outputs', or which is required for legal or regulatory compliance
Research data should be:

- Securely stored, identifiable, retrievable, accurate, complete, and reliable
- Compliant with legal and ethical requirements

[4] National Health Research Ethics Council (2015, https://www.health.gov.za/wp-content/uploads/2022/05/NHREC-DoH-2015-Ethics-in-Health-Research-Guidelines-1.pdf)
[5] The Office of Research Integrity has designed a tool to assist researchers in establishing whether their proposals fall within the definition of 'health research', available at https://forms.office.com/r/bJmFcgXtPY
[6] University of Oxford definition: https://researchsupport.admin.ox.ac.uk/governance/ethics/resources/consent
[7] Adapted from the NIH definition

- Where possible, able to be made available to others.[8]

A **Researcher** is any member of the university engaged in research (as defined as above). For avoidance of doubt, "member of the university" includes students, academic staff, and research staff.

Responsible conduct of research (RCR) is defined as "the practice of scientific investigation with integrity." It involves the awareness and application of established professional norms and ethical principles in the performance of all activities related to scientific research. Ethical and responsible conduct of research is critical for excellence, as well as public trust.[9]

4. Ethical, regulatory and legal requirements guiding the work of the committee

The work of the COM REC is guided, in the first instance, by the policies of the University of Cape Town relating to the ethical conduct of research. Primary among these policies are the

- UCT Policy for the Responsible Conduct of Research
- UCT Research Ethics Code for Research involving Human Participants

The COM REC is further bound by national legislation (particularly the National Health Act (2001) and its associated regulations relating to health research) and is cognisant of non-binding guidelines relating to the conduct of ethical research, including

- The Singapore Statement on Research Integrity
- The ASSAf POPIA Code of Conduct for Research
- The Cape Town Statement on Fairness, Equity and Diversity in Research
- The TRUST Code: A Global Code of Conduct for Equitable Research Partnerships

5. Meeting procedures

a. Frequency of meetings

The COM REC shall meet at least four times per year.

Meetings will be scheduled with at least four weeks' notice and the Servicing Officer will be responsible for sending calendar invitations to committee members.

It is however preferrable that a schedule of meetings for the year is prepared in advance, and that the dates for all planned meetings are entered in members' calendars as early in each year as possible, ideally in alignment with Senate EiRC meeting dates to allow for efficient reporting to the EiRC.

b. Format of meetings

While it is preferable that the committee meet in-person, the committee may meet in other ways (including online-only, or hybrid meetings formats) as necessary.

In the event of in-person meetings, the Servicing Officer shall secure an appropriate venue and communicate the venue in the Outlook meeting invitation and subsequent meeting information. In the event of online meetings, the Servicing Officer shall ensure that the meeting invitation includes the appropriate links to join the meeting.

[8] University of Oxford definition: https://researchdata.ox.ac.uk/university-oxford-data-management-policy

[9] University of California (Santa Barbara) Office of Research

In the event of hybrid meetings, the Servicing Officer shall secure an appropriate venue and communicate the venue in the Outlook meeting invitation and subsequent meeting information AND shall ensure that the meeting invitation includes the appropriate links to join the meeting.

The preferred platform for online and hybrid meetings is MS Teams.

c. Quorum requirements

Quorum for committee meetings is 50% +1 of the full membership (not including administrative or support staff or invited guests).

The quorum status of all meetings shall be noted by the Servicing Officer and must be recorded in the set of minutes for the given meeting.

If quorum is not met, a meeting may proceed, but any decisions taken in that meeting must be ratified by means of a Chair's circular.

d. Chair's Circular

A Chair's Circular may be issued to deal with any extraordinary or urgent business that arises in between scheduled meetings that needs urgent attention.

A Chair's Circular may also be issued to ratify any decisions of a committee meeting which was not quorate.

Non-quorate meeting

In consultation with the REC Chair and Exco, the Servicing Officer shall prepare the Chair's Circular for review by the Chair. If it is the case that a Circular is issued as a result of a non-quorate meeting, the Circular shall contain:

i. The original agenda of the meeting
ii. A short summary of each item
iii. Any decisions taken in the meeting, which need ratification.
iv. A deadline by which comments or objections can be submitted.

The Circular shall be sent, via email, to the committee with a commenting deadline at least seven (7) days after its distribution. All comments received in the commenting period shall be reviewed by the Chair and Exco, and a decision taken. Following the conclusion of the commenting period, and after consultation with the Chair, the Servicing Officer shall confirm that the commenting period has passed and indicate which decisions were ratified and if any have been held to the next meeting.

Extraordinary or urgent business

If it is the case that a Circular is issued as a result of extraordinary or urgent business, the Circular shall contain:

i. A summary of the business, including motivation for why it qualifies as extraordinary or urgent.
ii. Any supporting documentation.
iii. An invitation for discussion or comments.
iv. A commenting deadline.

The Circular shall be sent, via email, to the committee with a commenting deadline at least seven (7) days after its distribution. All comments received in the commenting period shall be reviewed by the Chair and Exco, and a decision taken. Following the conclusion of the commenting period, and after consultation with the Chair, the Servicing Officer shall confirm that the commenting period has passed and indicate the outcome of the circular.

e. Declarations of conflicts of interest and/or commitment and confidentiality

Each member will be asked to sign a conflict of interest and/or commitment and confidentiality agreement prior to attendance at a meeting. The declaration reads as follows:

> As a member (whether substantive, proxy, alternate, or co-opted) of the Commerce Research Ethics Committee (COM REC), proxy or co-opted staff member, or member of UCT staff, I agree to:
> - Maintain the confidentiality of all discussions, deliberations, records, and other information related to the functions of the COM REC.
> - **Not** participate in any case where I have a present or potential personal, professional, or financial conflicting interest or commitment. In such a case, I will be present only to provide information requested by the COM REC and will recuse myself during the discussion.

The business of a REC is confidential and should remain within the bounds of the committee. Committee members are expected to maintain the confidentiality of discussions held in meetings.

What may be communicated beyond the committee:

i. Outcome decisions on applications.
ii. Summarised discussions related to policies where umbrella bodies, such as the Senate Ethics in Research Committee (EiRC) have mandated faculty consultation on proposed policy revisions. Specific concerns may be communicated provided that explicit permission has been obtained from the party.
iii. Overall challenges and experiences of the committee may be reported to the EiRC at their meetings, to enable and enhance ethics governance and review throughout the institution.
iv. An REC Chair may consult other REC Chairs or the Office of Research Integrity when challenging situations arise or where those involved in the situation may be based in another Faculty.

It is the intention that confidentiality protects the business and independence of an ethics committee and the decisions it is empowered to take. Confidentiality should be seen to extend (as in the examples articulated in points i-iv above) to other RECs, the ORI and experts who may be consulted in order to make an informed, balanced and ethically informed decision on a given matter.

If it is necessary to consult an external, independent, expert on a given matter then a confidentiality or non-disclosure agreement should be signed before extensive consultations take place.

f. Non-attendance of committee meetings

Committee members shall make every effort to attend committee meetings.

If a member is not able to attend a committee meeting then that person shall, in advance, send apologies to the Servicing Officer, to be recorded in the meeting minutes. In the formal record this shall be recorded as a member sending apologies for the meeting.

A member of the COM REC on sabbatical or leave for more than six months may be replaced by an alternate member drawn from the same constituency as the substantive member with the agreement of the Chair of the COM REC. That alternative member will be expected to undergo the training requirements specified in 3(k) of the COM REC Terms of Reference, and to perform all duties that would normally fall to the substantive member.

If a committee member is absent (i.e., does not attend a meeting and does not send apologies in advance), for more than 2 meetings in a year, then the Chair may consult with the Dean of the Faculty of Commerce to seek a replacement for that member.

g. Preparation and dissemination of meeting agenda

In consultation with the REC Chair, the Servicing Officer shall send a call for agenda items to the committee no less than 3 weeks prior to a scheduled meeting.

Agenda items must be sent to the Servicing Officer, in writing, with a short description, any supporting documentation and identification of person responsible for speaking to the item. Agenda items must be sent to the Servicing Officer no more than 2 weeks prior to the scheduled meeting.

In consultation with the REC Chair the Servicing Officer shall prepare the agenda for the meeting. The agenda could include:

i. Welcome and apologies
ii. Confirmation of agenda
iii. Confirmation of minutes of the previous meeting(s)
iv. Matters arising (any items that have arisen out of previous meetings, still requiring resolution; if there are no arising matters then this section may be omitted)
v. Matters for noting (any items that committee members should take note of, but which do not require discussion at the meeting, if there are no matters for noting then this section may be omitted)
vi. Projects for review and decision
vii. Matters for discussion (this should include new matters brought to the attention of the committee either between meetings or as a result of the call for agenda items)
viii. Any other business (this section includes any previously unknown matters raised in (ii) above)
ix. Dates of forthcoming meetings
x. Conclusion (including the time at which the meeting terminated)

The agenda for a meeting shall be distributed to the committee, along with confirmation of format and any venue information, no less than 7 days prior to a scheduled meeting.

h. Recording, circulation and approval of meeting minutes

The Servicing Officer shall be responsible for recording the meeting either by use of the record function in an online or hybrid meeting, or by taking notes in an in-person meeting.

The minutes shall include a statement on whether quorum was met.

The draft minutes will be compiled by the Servicing Officer within 2 weeks of a meeting having taken place. The draft minutes will be sent to the Chair for review. The Chair shall have 1 week to review the draft minutes and recommended any revisions. Once the Servicing Officer has implemented the Chair's recommended revisions, the draft minutes shall be considered ready to be included in the agenda of the next committee meeting, for review, revision and/or approval by the whole committee.

In order to approve the minutes of a previous meeting one member shall propose that the minutes are approved, and another committee member shall second this proposal. Minutes may be approved subject to agreed changes discussed in the committee meeting.

The Servicing Officer shall note any revisions required by the committee and make those edits, following which the Chair shall sign the minutes.

The signed minutes will be kept on file by the Servicing Officer in the committee's document repository.

6. Review of research project applications

a. Principles

- All research projects originating in the faculty that involve human participants or subjects, or are to be conducted using secondary data that has not been exempted from ethical scrutiny (as described in Section 9 c) of these Standard Operating Procedures), are subject to ethical scrutiny by the COM REC.
- All such ethics applications are to be logged on the UCT research system, eRA. For audit reasons, no other ethics clearance procedure for research involving humans is permitted.
- No procedure exists for 'expedited reviews'. The COM REC has standards for completion of ethics reviews, specified in Section 7b, that will be adhered to. Failure to plan for the time to secure ethics clearance is not a valid ground for seeking expedited, or fast-tracked, review.
- The Faculty applies a tiered, risk-based, approach to applications for ethics clearance. A risk-based approach to review and approval of research means that research projects assessed as being of low ethical risk can be reviewed in a streamlined manner, whereas projects assessed to be of higher ethical risk are reviewed and discussed in more detail, typically at a convened meeting. Discussion and debate of the ethical aspects of projects at convened meetings is a critical skills development factor in the context of research ethics.
- In accordance with UCT policy, **no application for retrospective ethics review or approval will be considered**. This policy applies equally to staff and students in the Faculty.

b. Risk-based assessment

The main concern of a risk-based assessment is the evaluation of risks to participants in the proposed research, although risks to e.g., institutions, or researchers themselves, will also be considered. The following categories of risk all need to be carefully considered in an overall project risk assessment:

- Risk to participants.
- Risk to researchers, especially inexperienced student researchers or projects taking place in unsafe environments.
- Risk to stakeholders other than participants, including communities from which participants are drawn - this includes risk of stigmatisation or legal risks.
- Risk to the institution, which may include risks to reputation.

It is important to note that a project risk assessment must be made independently of steps taken to mitigate risk, such as compensation of participants time, or payment of travel costs. These actions do not alter the assessment of level of risk, but they may favourably alter the overall risk-benefit evaluation of the project.

c. Type of potential harm to participants in social and behavioural research

The research proposals that will come before the COM REC will typically involve social and/or behavioural research. When evaluating the risk-profile of any proposed study involving this kind of research, a risk-based assessment will take particular care to consider the following harms to participants that are most likely to arise in such studies.

- Psychological
- Social or economic
- Legal
- Loss of privacy and/or confidentiality

d. Review processes: Pre-screening questionnaire

At the bare minimum, a pre-screening questionnaire (PSQ) must be completed by all applicants who seek ethical clearance. If all the items in that questionnaire are answered in the negative, no further ethics application will generally be required, and a letter of exemption from full ethical review will be

generated by the eRA system. However, if any item is answered in the affirmative, a full ethics application will be required. Applicants may therefore wish to 'test' their proposed research against the questions in the PSQ, and if it appears that a full ethics application is likely to be required, the PSQ process can be by-passed, and a full ethics application initiated.

The current PSQ questions are shown in the text box on the next page.

Once submitted on eRA, the PSQ will be scrutinised by a Departmental Authority (DA) – that is, a member of the COM REC from the department from within which the applicant is based. Should the DA be conflicted in their ability to impartially scrutinise the PSQ (for example, because they (or a student they supervise) are the applicant, or they are a research collaborator of the applicant), the DA will declare a conflict of interest to the Chair of the COM REC, who will assign another member of the COM REC to review the PSQ.

The current PSQ questions are:- Does your project involve

- Direct interaction with human participants including via questionnaires, interviews, or experimental interventions?
- Analysis of secondary human data (data initially collected for another purpose) that contains any potential identifying personal information (with or without their knowledge or consent at the time)?
- Research on stored data or biological specimens where the researcher has access to codes that link the data to personal identifying information?
- Research that requires data matching or merging of databases where a personal identifier such as name, ID, student number, etc. will be used to link data?
- Observation of persons in a context where they would reasonably have an expectation of privacy – even if the individual is in a public place?
- Access to historical or other archives/repositories that contain identifiable information of living persons or confidential institutional or company information?
- Access to historical or other archives/repositories that contain information about deceased persons that may be regarded as sensitive?
- Social media research without direct consent in contexts where data subjects would not anticipate being researched, where their data may have been placed in the public domain without their knowledge or consent, or where the research questions could be regarded as ethically sensitive even if information is in the public domain?
- Quality assurance studies and program evaluations where you are likely to publish or present the results so that they can contribute to generalisable knowledge?
- Machine Learning and/or Artificial Intelligence algorithms?
- Sponsorship with the potential for conflicts of interest?

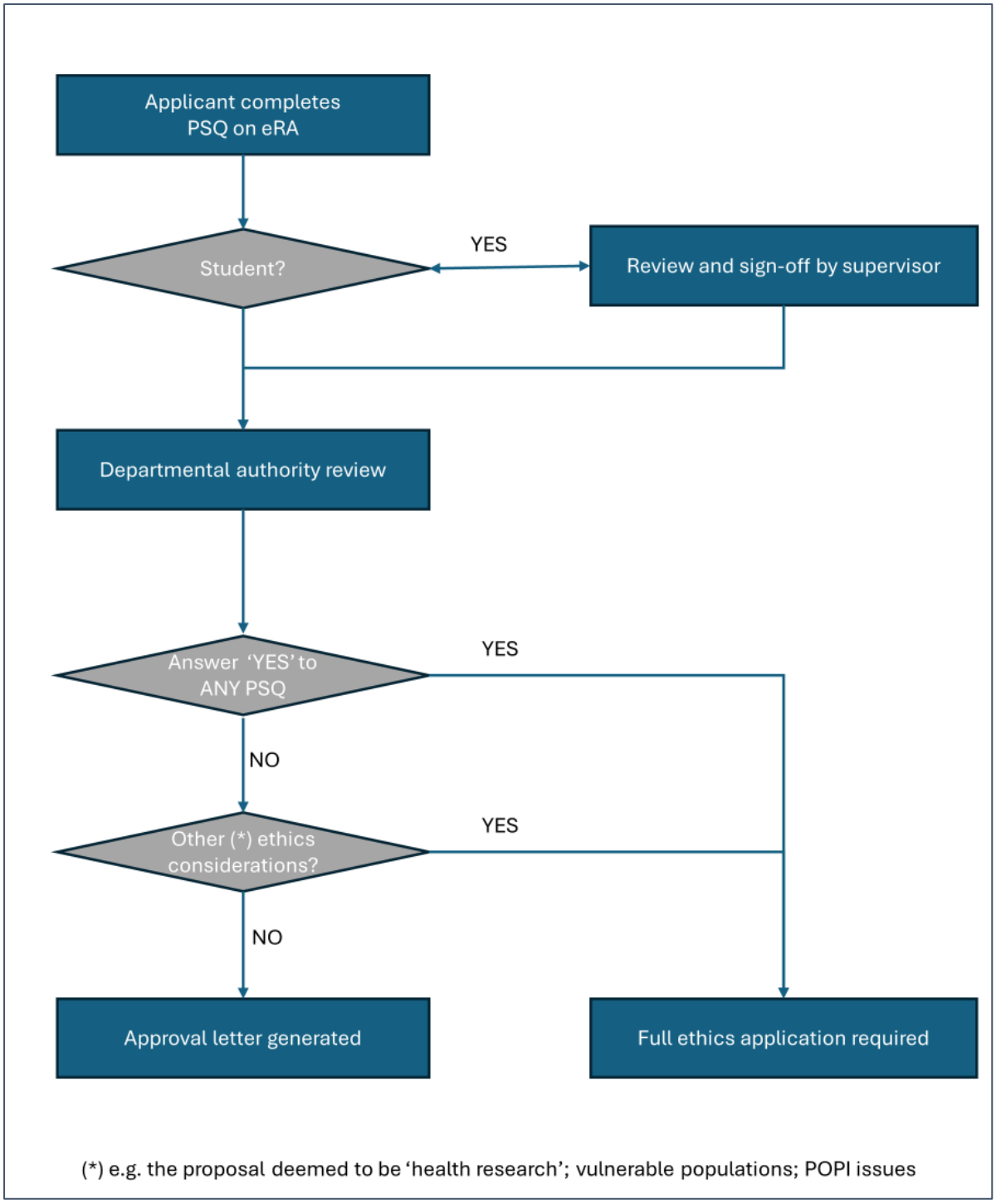
It is important to understand that even answering all the questions in the negative may still trigger a request for a full ethics application, if the DA is of the opinion that the research as described in the proposal nevertheless raises ethics concerns.

The steps in reviewing a PSQ submission are shown in the figure below. Processes are shown in blue, whereas decision points are shown in grey. A copy of the eRA process manual is available on the Commerce REC website.

1. The applicant completes a PSQ on eRA, including uploading a copy of the research proposal, and affirming all the declarations required.

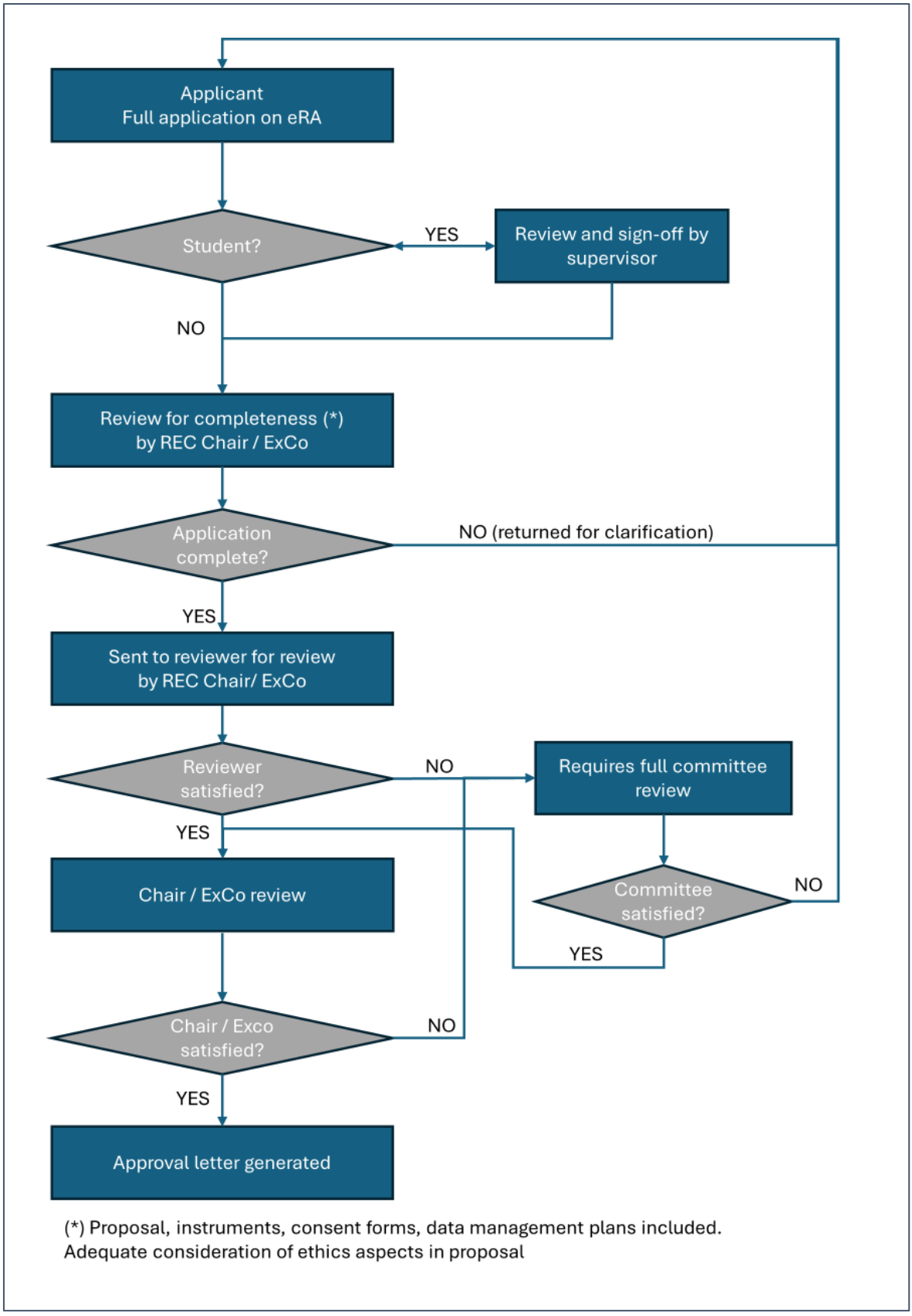
a. If the applicant is a student, they will have to enter the details of their supervisor who in turn will have to declare that they are satisfied with the student's submission before it can be reviewed
b. If the applicant is NOT a student, on completion of the questionnaire, it will be submitted to the DA.

2. The DA will review the submission.
    a. If any question has been answered in the affirmative, the DA will conclude the PSQ process, alerting the applicant that a full application is required.
    b. The DA will consider whether any aspect of the proposal MIGHT POTENTIALLY give rise to ethics concerns.
3. If neither 2a) nor 2b) above applies, the DA will sign off on the PSQ application, and a letter of approval will be generated within eRA, and the research project can commence.



e. Review process: Full review

The flow of the full review process is shown on the next page. As a full-review process, it is somewhat more complex than the PSQ review. Processes are shown in blue, whereas decision points are shown in grey. A copy of the eRA process manual is available on the Commerce REC website.



(*) Proposal, instruments, consent forms, data management plans included.
Adequate consideration of ethics aspects in proposal

1. The applicant completes a full ethics application on eRA, including uploading copies of the following documents, preferably in PDF format:
    - A full research proposal setting out the research question(s), methodology, and including a section describing the ethics aspects considered by the applicant;
    - The research instruments (questionnaires, interview guides, etc.) that will be deployed in the study;
    - The informed consent documents that will be administered;
    - A data management plan (DMP), setting out how the data will be collected, curated, accessed, and archived. A pro-forma DMP template is available at https://dmp.lib.uct.ac.za/ ;
    - A declaration of gatekeeper permissions required, and which either have been obtained, or will be obtained following granting of ethics approval. (See Section 7 g) for further information on gatekeeper permissions, and using UCT staff or students as research subjects)

    a. If the applicant is a student, they will have to enter the details of their supervisor who in turn will have to declare that they are satisfied with the student's submission before it can be reviewed
    b. If the applicant is NOT a student, on completion of the questionnaire, it will be submitted to the COM REC.
2. The Chair of the COM REC (or another member of the ExCo) will conduct an initial review the submission. At this stage, the focus of the review is on the completeness of the application in terms of the requirements specified above. However, the reviewer may also identify particular concerns or issues that they feel would be raised by the substantive reviewer, and suggest that these be addressed before the application proceeds to full review.
    a. At this point, the application may be returned to the applicant for further revision, or inclusion of additional information and/or documentation
    b. If the initial review indicates that the application is in order, the application will be forwarded to a member of the COM REC for full review.
3. The application is reviewed by a member of the COM REC. Procedures for selecting the reviewer are described in 7(a), and guidelines for reviewers are set out in Section 7c).
    a. If the reviewer identifies concerns with the application and proposal, the application is referred to the COM REC for deliberation as described in 5 below.
    b. If the reviewer is satisfied with the application and proposal, or if any issue identified is such that – at worst – it would result only in conditional approval, the application is forwarded to the Chair of the COM REC (or ExCo) for final approval, as described in 4 below.
4. The Chair of COM REC (or ExCo member) reviews the application and the review.
    a. If the Chair of COM REC (or ExCo member) disagrees with the reviewer's recommendation that the application should be approved, it is referred to the COM REC for deliberation as described in 5 below.
    b. If the Chair of COM REC (or ExCo member) is in agreement with the reviewer's recommendation for approval (or conditional approval), the application is approved (with or without conditions) for a defined period of time. The possible approval statuses and approval periods are described in Sections 7b) and 7e) below.
5. *[only necessary where the assessment raises ethical concerns, or the Chair of COM REC (or ExCo member) disagrees with the review offered in 3 above]* The application is provided to the full COM REC, with a cover note outlining the ethical concerns with the application. The COM REC will be asked to

7. Procedures associated with the review process

a. Assigning reviewers

The reviewer for a particular application will be assigned by the Chair of the COM REC, taking into account the following (hierarchical) factors:

Avoidance of conflict of interest:

Reviewers may not review their own submissions, that of their students, or collaborators

Domain expertise:

The reviewer should have cognate or domain expertise in the subject material covered by the application. Ideally, this should be a person within the same disciplinary field as that of the applicant, although the avoidance of conflict of interest shall always take precedence.

Methodological expertise:

Where an application requires specific methodological knowledge in order to assess the ethics implications, this requirement will be taken into account in assigning reviewers

Fair balance of work load:

Reviewers will be assigned bearing in mind the distribution of work, and the opportunities to develop skills in ethics assessment.

In practice, this means that even though falling under the COM REC, applications will tend to be referred to reviewers in the same, or cognate, department as the applicant. While departments may have their own processes for ethics review, and the purpose is not to duplicate extant policies and protocols, for audit reasons, all research projects requiring ethics approval must be lodged on eRA.

A committee member may decline to review a project assigned to them on the following grounds:

- Clear or perceived conflicts of interest or commitment,
- Lack of subject-matter expertise or,
- Inability to meet the review deadline owing to prior commitments.

If a reviewer declines to review an application, then a new reviewer shall be assigned to take on this task.

b. Time allowed to conduct reviews

The following times (in working days, from receipt) are allowed for the different stages of review:

- PSQ assessment: 2 days
- Initial assessment by Chair of COM REC (or ExCO member) before reversion to applicant, or allocation of primary reviewer: 2 days
- Primary review by reviewer: 5 days
- Full COM REC review (if required): 15 days
- Chair of COM REC final decision: 2 days

c. Review principles and criteria

The COM REC will review proposals in accordance with the UCT Guideline For Risk-Based Ethical Review of Research.

That guidance note is not reproduced in full here, save to note that the four tests deployed there will be utilised. Where the answers to each of the following four questions (largely related to those covered by the PSQ) is "no", the research can be regarded as being of no, or minimal, risk:

1. Does your research involve human participants, or their personal information?
2. Does your research involve human data that is coded or potentially identifiable?
3. Does your research involve indigenous or community knowledge systems?
4. Does your research involve social media platforms?

Research protocols that will be subjected to particularly careful evaluation would be those that

- Involve vulnerable groups
- Collect information that might be regarded as sensitive (or protected, in the terms of POPIA, including race, political views, or religious beliefs)
- Collect personal identifying information
- Intend to use race as a variable of analysis
- Involve recording of responses (including audio, video, or photographic)

Research protocols that will result in a referral to a full COM REC review include

- Any research that carries with it a waiver of informed consent
- Covert observations where privacy is reasonably to be expected
- Deception of any kind not disclosed in the informed consent documentation
- Asking respondents to report on illegal activities
- Those that may place the university at legal risk

d. Criteria for substantive reviews of applications

The eRA review worksheet will assist reviewers in completing the review. All submitted documents should be reviewed including informed consent documentation; advertisements, recruitment material or letters of invitation to participants; and research instruments.

Ethics review should include both administrative and substantive components. The administrative review ensures that all required documents or permissions are in place (e.g. assent forms for a project that involves children and consent forms for parents).

The substantive review should cover the following broad considerations:

- Potential social and scientific value.
    - While scientific validity is not the primary concern of an ethics committee it is important to note that projects that have methodological problems or appear to lack scientific rigour are ethically problematic as they waste resources, including those of participants, and can result in unreliable information becoming part of the scientific record.
- Suitability of research population: for example, avoiding selections based primarily on convenience, or targeting of certain groups without adequate justification.
    - In this regard, purposive / snowball / non-random sampling and/or selection of participants may raise ethical concerns as the results generated, or conclusions drawn from the study may not be reproducible or contribute materially to knowledge-generation.
- Adequacy of recruitment material and informed consent information and processes.
- Respect for participants throughout the course of the study by ensuring ability to withdraw if requested without consequences; that data privacy and security are adequately maintained; that additional study-related information is provided if such becomes relevant during the study, adequate debriefing if the study involves partial disclosures, etc.
- Favourable, or at least neutral, balance of risks and potential benefits.
- Researcher competency (or supervision by a competent researcher for the given methodology).
- Community engagement throughout the course of the project if applicable, including dissemination of project outcomes.
- Review of plans for ongoing ethics reflection by the research team, during the project, if applicable

e. Recommended project outcomes

At the end of a review process, the following outcomes are possible

- "Approved active" – the project can start
- "Approved with conditions" – the project is approved, but additional requirements (e.g. securing gatekeeper permissions) must be met
- "Not approved" – the project may not start

Decisions will be made by the Chair of the REC (or ExCo member) when their view is congruent with that of the reviewer's recommendation to approve the project. Where the reviewer refers the application to a full meeting of the REC, or where the view of the Chair of the REC (or ExCo member) is not aligned with a reviewer's recommendation to approve the project, the decision will fall, first, to the full COM REC, and thereafter to the Chair of the REC.

The Chair of the REC (or the ExCo member approving the application) will capture the committee's comments on the eRA system and move the application to a final status. This will allow the applicant to generate an outcome letter. Thereafter, the applicant will receive a notification, advising that they should log on to the eRA system and download the outcome letter. If an application is approved, the outcome letter is the clearance for the researcher to commence with the study.

Where a project is "not approved", sufficient feedback will be given to the applicant to allow them to reconsider their project, or its protocols, with a view to resubmitting the application.

f. Periods of approval

Ethics approval will be granted for a maximum period of 13 months, that is to the last day of the same month in the year after the approval of the research proposal. Where the project is time limited (e.g. a Master's research project with a clearly specified deadline for submission, ethics approval will end no more than two (2) months after that deadline.

Where a project is likely to extend beyond the initially-specified date of termination of approval, the responsibility rests on the applicant to ensure a timely renewal (see Section 6(i)) to ensure continuity of ethics approval.

g. Gatekeeper permissions

Ethics applications that seek to recruit employees of a company (in that capacity) into a study require permission from the company to do so.

Likewise, research proposals that seek to make purposeful use of students or staff from UCT must comply with the relevant UCT policies and approval procedures regarding the use of UCT students or staff as research subjects. These procedures are detailed on the UCT Office of Research Integrity website.

h. Amendments to approved projects

Any change to a COM REC approved research project requires the submission of an amendment request, using the eRA system. Such requests must identify whether the amendment is of a minor or a major nature.

Minor amendments: do not change the risk profile of the project and include changes to research sites; investigators, especially the lead investigator; and minor changes to research methodology, such as adding an additional research instrument. Minor amendments will generally be reviewed and approved via an expedited process involving either the Chairperson, or member(s) to whom this task is delegated.

Major Amendments: involve substantive changes to the project that may alter the ethical risk profile of the research, as described in the "UCT Guideline for Risk-Based Ethical Review of Research". Major amendments will be reviewed as new proposals.

i. Renewals of approved projects

Towards the end of an approved period, an applicant wishing to renew approval of a project must lodge a request for renewal of ethical clearance. In the absence of a dedicated option within eRA to apply for renewal, a new application must be submitted, clearly linking the new application to the preceding application (through both recording the previous approval identifier, and – in the title of the application – including of the text "[RENEWAL]").

If the renewal application includes amendments (as described above), approval for renewal and amendment must be sought concurrently.

j. Reporting adverse or unanticipated events

A distinction is drawn between serious adverse events, and other adverse events. A serious adverse event is any event tin research that results in any of the following:

- Death
- A life-threatening incident
- Hospitalisation
- Disability
- Breaches of confidentiality, information, or data security that may place participants at risk of harm.

Other adverse events would include

- Breaches of information or data security which do not place participants at risk of harm
- Physical, physiological, or psychological stress as a result participation in the research

Where a proposed project is identified, either by the applicant or the COM REC, to foreseeably carry the risk of inducing adverse events among participants the study protocol must include

- Instructions to the researcher/fieldworker on what to do if such an event occurs (e.g. to stop an interview immediately);
- Information that can be provided to the participant on how to seek assistance (and if this is to be provided by an external organisation, that arrangements for referral have been made in advance);
- Mechanisms to report serious adverse events to the Chair of the COM REC within 48 hours of the occurrence. Reporting of serious adverse events must include
    - Appropriate identifying information for the research protocol, such as title, investigator's name, and eRA reference number.
    - A description of the adverse event/incident/experience/outcome.
    - An explanation for determining that the adverse event/incident/experience/outcome indicates an unanticipated problem.

- A description of any proposed changes and corrective actions that will be taken in response to the unanticipated problem.

The principal investigator's competence is relied upon by the COM REC in order to determine the problem's or event's cause, seriousness, and if it was anticipated. Additionally, researchers must advise whether a modification to the protocol is required to reduce participant risks, whether the consent form needs to be updated to reflect this risk, and whether people in the study need to re-consent considering this risk.

If there are immediate risks to participants, the Chair or Deputy Chairs may take one or more of the following actions:

- Suspend COM REC approval to ensure the safety of participants.
- Call an emergency COM REC meeting to act on the report.
- Request additional information from the principal investigator or others.

Adverse events that are not serious and do not require immediate action will be reviewed by the COM REC Chair or Deputy Chair.

If serious adverse events are reported that are serious and require immediate action, the Chair or full committee may request further information or require the following remedial actions:

- Revise the protocol.
- Modify inclusion or exclusion criteria to mitigate the newly identified risks.
- Suspend enrolment of new participants.
- Suspend procedures in currently enrolled participants.
- Modify informed consent documents to include a description of newly identified risks.
- Provide additional information about newly recognized risks to previously enrolled participants.
- Suspend approval.
- Terminate approval.

k. Suspension or termination of projects

In addition to the circumstances outlined in Section 7(j) that might result in a project being suspended or terminated, reported or alleged breaches of research conduct policy in terms of Sections 12 and 13 below might result in a project's suspension or termination.

The decision to suspend or terminate (pending further investigation and/or remediation) will be taken by the COM REC (as a whole).

l. Reciprocal recognition of prior ethics approvals

Circumstances might arise where

i. A member of the Faculty of Commerce is a collaborator on a multi-institution project which has been granted ethics approval from one (or more) lead institutions; or
ii. An academic or student at another institution wishes to access UCT staff and/or students for their research project

In (i), the member of the Faculty of Commerce is obligated to apply for ethics clearance from the COM REC, irrespective of other existing ethics clearances.

In (ii), the external applicant has to seek ethics approval from the COM REC as a pre-condition for applying to access UCT staff and/or students for their research. In this case, the external applicant is expected to have secured ethics approval from their home institution. In order to be able to apply for

ethics from the COM REC, the external applicant will have to apply for third-party network access in order to lodge an application on eRA.

In both cases, the COM REC, in assessing such an application, will take due cognisance of the ethics approval already granted, but has to establish the ethical risks associated with the project independently thereof.

8. Informed consent

The UCT Research Support page provides numerous resources related to research integrity, including informed consent. Generic templates (for example, Cornell University's template for Social and Behavioural Research Projects) can offer useful guidance, but researchers would nevertheless need to adapt any such template to ensure compatibility with any particulars of their research project.

In general, minimal requirements for informed consent should ensure that:

- participants are given a full and accurate summary of their expected commitments, for the lifespan of the research project;
- where participants are minors, that a legal guardian has provided consent;
- the purpose or goal, as well as possible costs and benefits, of the research is made clear;
- participants are aware of the manner in which the data might be published, including considerations such as the identifiability of participants;
- participants have clear information regarding the extent of their access to publications resulting from their participation, as well as contact details if future engagement is required;
- the nature of any future access to research outcomes is provided;
- participants are aware of their right to withdraw from the research at any time;
- participants are provided contact details for relevant support channels, where necessary.

9. Data

This section is to be read in conjunction with UCT's Research Data Management Policy.

a. Data collection, management and storage

Applications for ethics approval are expected to provide a data management plan (DMP) setting out how the data will be collected, stored, curated, and archived. The DMP should further specify who will have access to data (especially data that may yet to be de-identified), and how those data will be securely stored and archived.

b. Re-use of own data

Re-use of data (discussed in this paragraph) is distinct from the Use of Secondary Data for Research Purposes described in c) below.

Re-use of own data refers to the use of data that have been collected – following ethics review by the COM REC - by the same investigator(s), research group,or a subset thereof, for subsequent research.

Use of data collected previously (provided that the collection thereof was subjected to appropriate ethics review and approval) may be re-used for research purposes provided the original application made provision for re-use of data, and participants were appropriately informed that data collected as part of the original exercise might be reused for academic research purposes. However, as with the use of (other) secondary data, researchers should be alert to the fact that journals are increasingly asking for proof of ethics clearance for the paper submitted. An ethics clearance in respect of the original data collection may not suffice for these purposes. While in most cases, the re-use of data

(subject to the caveat above) should not be regarded as contentious, researchers are advised to seek guidance from the COM REC should they wish to re-use data collected under a previously-approved ethics clearance. Applications for research ethics clearance that seek to re-use such data should be accompanied by the original ethics approval. While the COM REC must satisfy itself that the data to be used are indeed covered by the prior ethics approval, the evaluation of the application will concentrate specifically on the intended use of those data, and whether that use conforms with ethical standards.

c. Use of secondary data

In contrast, the use of Secondary Data for Research Purposes covers the use of data that have been collected, from humans, by entities not connected to the applicant for ethics clearance.

The most common sources of such secondary data are de-identified official government datasets (e.g. Demographic and Health Survey data, or other national survey data). The use of de-identified data from secondary data sources (e.g. official government data; or survey data collected by government agencies) is covered by the Faculty of Commerce Practice Note on Secondary Data. *Inter alia*, this Practice Note records that
"Even though formally exempted, researchers are encouraged to nevertheless apply, initially using the Pre-screening Questionnaire for the sake of prudence, and/or if their research or its future publication requires or might foreseeably require an approval number from the Ethics in Research Committee".

Ethics applications that seek to make use of de-identified data from data sources not explicitly covered by the Practice Note (or which seek to make us of data that are NOT explicitly stated to be de-identified) will be subjected to particularly careful review, and the COM REC may request that a valid ethics approval be provided regarding the collection of the original data.

Studies that seek to link multiple secondary data sources from a common (even if anonymised or hashed) identifier that may result in the ability to identify individuals will attract careful scrutiny.

The COM REC will review and update the Practice Note on Secondary Data every 2 years.

d. Third-party and/or proprietary data

Research ethics applications that seek to make use of third-party and/or proprietary data that do not relate to persons, or contain personal data, will generally be approved, although researchers should ascertain their rights to either publish, or submit for examination for degree purposes, prior to commencement of the study. In this regard, attention is drawn to the provisions relating to confidential data submitted for degree purposes, set out in rule G30 of the UCT General Rules.

e. Use of historical data of unknown or potentially dubious origin

It may, occasionally, be the case that the provenance and/or ethics status of data that a researcher or group of researchers wish to use in a study is unclear, or cannot be conclusively determined. In such situations, the researcher (or Principal Investigator) must seek guidance from the COM REC before submitting a proposal for research ethics review. Full details of where the data were obtained, and any material information known to the researcher (or Principal Investigator) must be supplied to the COM REC, who will make a binding decision as to the probity of the data that is wished to be used.

10. Privacy and confidentiality

The COM REC expects that all research ethics applications to cover the measures in place to protect the privacy and confidentiality of all participants. This includes, but is not limited to,

- Minimising risk to participants' health, safety, and well-being;
- Methods to ensure that analytical datasets are anonymised or de-identified where necessary
- Maintaining confidentiality of participants where those participants have a legitimate expectation of confidentiality;
- Protection of data held on participants. This applies even more so when voice or video recordings are made, or photographs of individuals are taken, as part of the data collecting process;

In cases where it will not be possible to prevent the identification of a research participant (e.g. owing to their position, or title), the submitted informed consent documentation must ensure that the participant is aware of the implications of their participation.

11. Research with vulnerable participants

Research ethics applications involving vulnerable participants will be subject to particular scrutiny to ensure that all necessary protections for those participants is in place. The definition as to what constitutes a 'vulnerable participant' is highly context-dependent, although the following groups of participants will – almost without exception – be regarded as 'vulnerable':

- Minor children
- Persons with physical or mental impairments or any other condition, including HIV/AIDS, that might be stigmatised
- Persons with low-education levels
- Persons at risk of exploitation or victimisation as a result of their participation in the study

12. Breach of ethics approval, policy and non-compliance

Breaches of ethics approval, ethics policy, or non-compliance will be handled in terms of the UCT Policy for Breach of Research Ethics Codes and Allegations of Misconduct in Research.

Until such time as the Faculty of Commerce has developed and implemented faculty-specific committees that are consistent with this policy, and in the absence of the appointment of the Commerce Faculty Advisor on Research Integrity, as described in the Commerce Faculty Research Misconduct Policy,

13. Dispute resolution and appeal mechanisms

a. Dispute resolution

When a researcher is not satisfied with a decision or does not agree with a decision made by the COM REC they have a right to dispute the decision. An appeal can be requested for procedural or substantive reasons. The responsibility to justify the grounds for the appeal rests with the researcher. Such appeals must be made, in writing to the COM REC servicing officer, within ten (10) calendar days of receiving the outcome of their ethics application.

Acceptable grounds for appeal include demonstrable procedural errors and substantive challenges to the justification for the decision.

b. Appeal mechanisms

Researchers who wish to appeal the decision of the COM REC must provide a detailed account of any perceived procedural errors and/or arguments against the decision. The motivation must be submitted via email to the COM REC servicing officer, who will include it in the agenda of the next COM REC meeting. If the committee needs further clarification from the researcher, the Chair (through the COM REC Servicing Offier) will invite the researcher to attend the next scheduled meeting. The researcher's participation will be beneficial if the research itself is complex and needs further explanation.

14. Procedures for raising concerns or complaints related to research projects

Concerned parties may raise complaints or issues related to the conduct of the Commerce REC or of a project approved by the Commerce REC in accordance with the UCT Policy for Breach of Research Ethics Codes and Allegations of Misconduct in Research (colloquially called the Research Misconduct Policy), or the Whistleblowing Policy.

a. Reporting under the research misconduct policy

Annexure 1 (page 8) of the Research Misconduct Policy describes procedures for a complainant:

1.1. A person who suspects research misconduct should take responsible action in terms of this policy and procedure and contact the faculty research integrity advisor (F-RIA) or the ORI, to either seek confidential advice or to indicate that they wish to lodge a complaint.

1.2. In some instances, an informal discussion may be sufficient to resolve the matter. However, the F-RIA must ensure that potentially valid concerns are not dismissed or minimised.

b. Reporting under the whistleblowing policy

Section 7.1. (page 6), of the Whistleblowing Policy describes an internal route for a complaint as follows: *"Any concerns or disclosures shall preferably first be made to the line manager or responsible University official, or their superior, unless the whistleblower is for some reason not comfortable taking this reporting route. As an alternative, a report can be made directly to the UCT Risk, Compliance and Relationship Management Director or the Internal Audit Director. The advantage of internal reporting is that it facilitates effective communication between university officials and the whistleblower, and this in turn enables the efficient and effective investigation and resolution of matters.*

In making a report internally, a whistleblower may request that their identity remain confidential amongst only those with a legitimate need for the information. In this case, the whistleblower must equally make every effort to ensure that they do not themselves cause their identity to become common knowledge."

15. Protection of whistleblowers

UCT's Whistleblowing Policy states as follows:

" The University of Cape Town (UCT) intends to maintain a culture of integrity in all its work and dealings. As a large and complex institution that engages and deploys significant resources, unlawful and irregular activity can cause significant harm to the University. This means that the risk of unethical activity to UCT resources and to its reputation must be a cause for ongoing vigilance. More specifically, potential and actual wrongdoing needs to be promptly identified in order for any arising loss to be minimised, and that measures to deter recurrence can be instituted. This requires that all stakeholders are aware of and able to discharge their duty to bring any suspicions and knowledge of unethical activity to the attention of the University.

Accordingly, UCT has established and maintains channels for the reporting of wrongdoing by all stakeholders, both internal and external. As an employer, the University is committed to enabling its staff and contractors to fulfil their legal obligation to report suspicions or knowledge of fraud, corruption or other malpractice within UCT without fear of retaliation. The effective deterrence, detection and remediation of wrongdoing at UCT is the overriding objective of this Policy. Its implementation plays a key role in ensuring that the University fulfils its obligations in terms of the regulatory framework within which it operates, and in terms of its duties to the communities and society that it serves." (Whistleblowing Policy, page 2)

Should anyone wish to raise concerns about a research project approved by the Commerce REC, they may do so in accordance with the whistleblowing policy.

Please consult page 7 of the aforementioned policy for routes to report concerns. **Calls should be made to 0800 650 000, which is toll-free from landlines. Alternatively, an SMS can be sent to 33490 and a whistleblowing hotline information agent will call back.** There are other routes to report concerns described in the policy document.

16. Authorship and acknowledgement

The template document for Faculty Standard Operating Procedures (SOP) was developed by Mrs Paula Saner (Manager, Office of Research Integrity). Each Faculty has permission to edit and adjust the template to suit faculty needs and practices. The COM REC SOP were drafted in accordance with the template by Professor Tom Moultrie in April 2024 and submitted to the Faculty Board in August 2025.

The National Health Research Ethics Council (NHREC) Ethics in Health Research Guidelines (2015) provided useful information which has been incorporated into this SOP document.

This SOP has also borrowed text and processes from the approved IFHREC SOPs, drafted by Mr Jacques Rousseau, and approved in 2024.

Thanks go to the internal audit team for recommendations for improving ethics governance structures at UCT through strengthening and harmonising (where possible) documentation and processes.